REMARKS

I. Summary of the Office Action and this Reply

Claims 1-11, 13-16 and 28-31 are pending in the application. Allowable subject matter has been acknowledged in claims 4-11 and 13-16.

The Examiner has rejected claims 1-3 and 28-31 under 35 U.S.C. §102(b), asserting that such claims are anticipated by U.S. Patent No. 5,279,582 to Davison et al. ("Davison"), or alternatively, by U.S. Patent No. 5,147,303 to Martin ("Martin").

In this Reply, claim 3 is amended. No new matter is added; support for the amendment may be found, *inter alia*, in the specification at page 14, lines 19-23, page 19, lines 1-18, and Figure 9.

II. Response to 102 Rejections

A rejection under 35 U.S.C. §102 is proper only if each and every element of the claim is found in a single prior art reference. MPEP § 2131. The Examiner has rejected claims 1-3 and 28-31 under U.S.C. § 102(b), asserting that each and every element of these claims are found in both Davison and Martin.

Claim 1

Independent claim 1 recites "a retraction mechanism that automatically moves the needle to the retracted position responsive to releasing the base from the site surface." Contrary to the Examiner's assertion on page 2 of the Action, Davison does not disclose such a retraction mechanism.

Davison discloses a syringe 10 that includes a barrel 12, a plunger 14 slidable

within the barrel, a needle 16 affixed to the end of the barrel, an adapter sleeve 18 and a spring 20. See Figures 1 and 2. Figure 7 illustrates the use of the syringe 10 to inject medicine through skin D. As described in Davison at col. 5, lines 31-40:

> The open end 34 of the sleeve is placed against the skin at the injection site. The barrel 12 is then pushed toward the skin. The spring 20 is compressed, allowing the barrel to slide though the sleeve and the needle to pierce the skin while the sleeve is in a retracted position and the needle extends beyond the sleeve. When the injection is completed, the barrel and needle are withdrawn, and spring 20 causes the sleeve to return to its protective position enveloping the needle.

Accordingly, Davison does not disclose "a retraction mechanism that automatically moves the needle to the retracted position responsive to releasing the base from the site surface." Upon careful examination of the Figures and description of Davison, it is apparent that the distal end of the needle 16 will be "retracted" into the sleeve 18 before sleeve 18 leaves/is released from the skin surface. More specifically, as the barrel and needle are withdrawn after an injection, the sleeve remains pressed against the skin by the spring 20. Further, the sleeve 18 remains pressed against the skin by the spring 20 until the needle 16 has been fully retracted into the sleeve, i.e., until the barrel's flange 22 abuts the stop flange 40 of the sleeve 18. After the flange 22 abuts the stop flange, continued withdrawal of the barrel 12 will result in release of the sleeve 18 from the skin's surface. However, at this point, the needle has already been fully moved to the retracted position. See Figures 1 and 2. Accordingly, the movement of the needle to the retracted position is not responsive to releasing of the device's base

from the injection site surface. This is directly contrary to the claim language, which requires a retraction mechanism that automatically moves the needle to the retracted position responsive to releasing the base from the site surface, and not before release of the base from the site surface as in the Davison device.

Figures 9-11 of Davison illustrate an alternate embodiment that operates in a similar manner. With respect to this embodiment, Davison states "The spring 44 is dimensioned such that when the sleeve is in the extended position, the spring will be in an uncompressed relaxed state." Col. 6, lines 15-22. The spring is compressed during injection in a manner similar to that described with reference to Figures 1-7. See Figures 7 and 10.

With reference to Fig. 12, Davison states "[w]ith this arrangement, spring 44 is preferably always in compression to urge the sleeve 18 into a protective position enveloping the needle." Col. 6, lines 23-30.

Thus, in these alternative embodiments, the spring similarly maintains the sleeve against the site surface until the needle has been moved to the retracted position, and releasing of the device from the site surface occurs after the needle has been moved to the retracted position.

Therefore, Davison lacks the claimed retraction mechanism, and thus not all elements of claim 1 are found in Davison. For at least this reason, reconsideration and withdrawal of the rejection of claim 1 over Davison are requested respectfully.

Further, there cannot be motivation to modify Davison to provide the claimed invention because doing so would render the Davison device inoperable for its intended purpose and/or change the principle of operation of the Davison device, which relies

upon the spring to maintain the sleeve 18 against the skin as the device is withdrawn, and which relies upon the larger flange 22 to interfere with stop flange 40 to prevent the barrel 12 from being withdrawn from the sleeve 18, which in turn causes withdrawal of barrel 12 to result in withdrawal of the sleeve 18 from the site surface. See Col. 5, lines 1-3; Figures 1, 2 and 7.

With respect to the alternative rejection over Martin, Martin discloses a disposable safety syringe 10 that includes a sheath 12 for receiving a cylinder 16 of a conventional syringe. A spring 40 surrounds the cylinder 16, and a latch 54 is provided to latch the spring 40 and cylinder 16 in a downward position with the sheath 12 prior to and during use of the syringe, as shown in Figure 2. Col. 3, line 47 – col. 4, line 19. The spring 40 prevents the cylinder 16 from sliding out of the sheath 12. To release the cylinder 16, it will need to be pushed inward against the spring 40. Col. 4, lines 31-41. When the syringe is to be disposed of, the user depresses the syringe's plunger 28 to allow an upper end 42 of a spring 40 to release the latch 54 and enable spring 40 to push against flange 44 to raise cylinder 16 out of sheath 12, as shown in Figure 3. As a result of the upward movement of the cylinder 16 out of the sheath 12, the needle 24 is pulled into the sheath 12. Col. 4, line 67- col. 5, line 15.

Accordingly, the Martin device includes structures that result in retraction of the needle into a sheath. Therefore, the Martin device might be argued to include a retraction mechanism that automatically moves the needle to the retracted position. However, any such mechanism in Martin does not automatically move the needle to the retracted position "responsive to releasing the base from the site surface", as required by claim 1. Instead, the Martin device relies upon depression of the syringe's plunger to

release the latch and restriction of the needle, which could be performed before or after release of the device from an injection site's surface. Further, such restriction is not responsive, in any cause-and-effect relationship, to releasing of a device's base from a site surface. Accordingly, Martin lacks the claimed retraction mechanism, and thus not all elements of claim 1 are found in Martin.

Further, there cannot be motivation to modify Martin to provide the claimed invention because doing so would render the Martin device inoperable for its intended purpose and/or change the principle of operation of the Martin device, which relies upon a manually operated plunger-actuated spring-biased mechanism for retracting the needle into the sheath.

Claims 2-11 and 13-16

Claims 4-11, and 13-16 have been recognized as allowable.

Claims 2 and 3 depend from claim 1 and are likewise allowable for the reasons set forth above for claim 1. Additionally, claim 3 is amended herein to recite that the "retraction mechanism locks the needle in the retracted position after moving the actuator to the actuated position to prevent a repeated movement of the needle to the extended position." This is neither taught nor suggested by the cited art. More specifically, the Davison device may cause moving of the needle to a retracted position after injection, but it does not affirmatively lock the needle in the retracted position to prevent a repeated movement of the needle to the extended position, e.g. to deliver another injection. Instead, the Davison device could be reused to perform another injection, which is generally undesirable. The Martin device includes a spring-biased

pivotably mounted disc 22 to close an opening 26 in a sealing cap portion 20 of the sheath after an injection, it does not lock the needle in the retracted position; the needle is still free to move within the sheath until the point of the needle interferes with the disc 22. See Figure 3. This movement is due to clearance space between the point of the needle and the disc, when the disc is in position to close the opening. This space between the needle's point and the disc 22 is required to provide clearance permitting the disc 22 to pivot to close the opening 26. See Figures 2 and 3. Accordingly, there cannot be motivation to eliminate such space such that the needle is locked and prevented from moving within the sheath, because doing so would render the pivotable disc inoperable for its intended purpose, in that the disc would interfere with the needle during pivoting and thus would not close.

Claim 28

Independent claim 28 recites "a retraction mechanism that automatically moves the needle from the extended position to the retracted position, the retraction mechanism being configured to begin moving the needle to the retracted position in response to removal of the needle device from the surface." This is clearly not taught or suggested by Davison or Martin, for reasons similar to those discussed above with reference to claim 1. As discussed above, and in Davison, the Davison device's needle begins to be withdrawn into the retracted position well before the sleeve 18 is removed from the skin surface. As a result of the spring-biasing of the sleeve 18, withdrawal of the needle into the "retracted" position begins before the Davison is removed from the skin surface. The Davison device thus does not begin moving the needle in response

to removal of the needle device from the surface. Accordingly, Davison lacks the claimed retraction mechanism, and thus not all elements of claim 28 are found in Davison.

The Martin device includes structures that result in retraction of the needle into a sheath, but any such mechanism in Martin does not automatically move the needle to the retracted position "responsive to releasing the base from the site surface", as required by claim 28. Instead, the Martin device relies upon depression of the syringe's plunger to release a latch, which is performed entirely independently of any release of the device from an injection site's surface. In other words, the retraction in the Martin device is not responsive, in any cause-and-effect relationship, to releasing of a device from a site surface. Accordingly, Martin lacks the claimed retraction mechanism, and thus not all elements of claim 1 are found in Martin.

Further, there cannot be motivation to modify the Davison or Martin devices to provide the claimed invention because doing so would render the those device inoperable for their intended purposes and/or change their principles of operation, as discussed above with reference to claim 1.

For at least these reasons, reconsideration and withdrawal of the rejections of claim 28 are requested respectfully.

Claims 29-31

Claims 29-31 depend from claim 28 and are likewise patentable for similar reasons.

Additionally, claim 29 recites a locking mechanism that prevents the needle from

moving back to the extended position once the needle has been moved from the extended position to the retracted position. Thus, claim 29 is believed patentable for reasons similar to those set forth above for claim 3.

For at least these reasons, reconsideration and withdrawal of the rejections of claims 29-31.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants believe claims 1-11, 13-16 and 28-31 to be patentable and the application in condition for allowance. Applicants respectfully request issuance of a Notice of Allowance. If any issues remain, the undersigned requests a telephone interview prior to the issuance of an action.

Respectfully submitted,

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